(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within 10 days of the request, but no later than 5 days before the end of the review period.

(6) All test data described under paragraph (a) of this section are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new microorganism that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in §725.25(h), and in addition to the information required by §725.155(c)(3), any person who submits a MCAN must describe the following data, including any data from a health and safety study of a microorganism, if the data are related to effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the microorganism, of any microbial mixture or article containing the new microorganism, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the microorganism.

(2) Data that must be described include data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed in paragraph (b)(1) of this section.

(3) The description of data reported under paragraph (b) of this section must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not available in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described in paragraph (b) of this section are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the MCAN is submitted.

§725.170 EPA review of the MCAN.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of MCANs submitted under this subpart:

(a) Length of the review period. The MCAN review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete MCAN, or the date EPA determines the MCAN is complete under §725.33, unless the Agency extends the period under section 5(c) of the Act and §725.56.

(b) Notice of expiration of MCAN review period. (1) EPA will notify the submitter that the MCAN review period has expired or that EPA has completed its review of the MCAN. Expiration of the review period does not constitute EPA approval or certification of the new microorganism, and does not mean that EPA may not take regulatory action against the microorganism in the future.

(2) After expiration of the MCAN review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the microorganism even if the submitter has not received notice of expiration.

(3) Early notification that EPA has completed its review does not permit commencement of manufacture or import prior to the expiration of the 90–day MCAN review period.

(c) No person submitting a MCAN in response to the requirements of this subpart may manufacture, import, or

process a microorganism subject to this subpart until the review period, including all extensions and suspensions, has expired.

§ 725.190 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new microorganism for nonexempt, commercial purposes for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement (NOC) of manufacture or import.

(b) *When to report.* (1) If manufacture or import for nonexempt, commercial purposes begins on or after May 27, 1997, the submitter must submit the NOC to EPA no later than 30 calendar days after the first day of such manufacture or import.

(2) If manufacture or import for nonexempt, commercial purposes began or will begin before May 27, 1997, the submitter must submit the NOC by May 27, 1997.

(3) Submission of an NOC prior to the commencement of manufacture or import is a violation of section 15 of the Act.

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claimed microorganism identity confidential in the MCAN, and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and resubstantiated in accordance with § 725.85(b). Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(d) *Where to submit.* All notices of commencement must be submitted to EPA in a manner set forth in this paragraph.

(1) *Older notices.* Notices of commencement for a MCAN submitted before April 6, 2010 must be submitted on paper either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(2) *Newer notices.* For MCANs submitted on or after April 6, 2010, EPA will accept notices of commencement only if submitted in accordance with this paragraph:

(i) Notices of commencement may be submitted on paper on or before April 6, 2011. All paper-based notices of commencement must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper notices of commencement must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(ii) Notices of commencement may be submitted as electronic files on optical disc on or before April 6, 2012. All notices of commencement submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic notices of commencement must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(iii) Notices of commencement may be submitted electronically to EPA via CDX on or after April 6, 2010. After April 6, 2012 all notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN reporting software. See 40 CFR 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

[62 FR 17932, April 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]